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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,527	06/27/2002	Jialong Yao	P67678USO	4563

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EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,527	YAO ET AL.	
	Examiner	Art Unit	
	Medina A Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-34 are pending and are examined.

Sequence Listing

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and amino acid sequences set forth in 37 CFR1.821 (a)(1) and (a) (2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

The CRF and paper sequence listing of 08/19/02 have been entered. However, the sequences, for example, on page 17, lines 21-22, and 33 have not been identified by SEQ ID NO:. Also, the sequences of Figures 2, and 6 have not been identified by SEQ ID NO: in the Brief Description of the Drawings on pages 5-6 of the specification. Applicant is respectfully requested to identify the sequences presented in the figures and on page 17, or to submit a new Sequence Listing that comprises said sequence.

Specification

The disclosure is objected to because of the following informalities: for example, page 8, lines 22, 27, and 31 of the specification contains an embedded hyperlink directed to an Internet address. The use of hyperlinks and/or other form of browser-executable code are not permitted under USPTO current policy because the content of such links are subject to a change, resulting in the introduction of New Matter into the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser- executable code. See MPEP 608.01.

Claim Objections

The claims are objected to because it is unclear why the *MdPI* and the *MdAP3* ate in italics.

At claim 3, 5-12, 14-15, 17-18, "A" should be changed to ---The-- because each claim refers to a previous claim.

At claim 19, "a" should be changed to --the--- because it refers to a previous claim.

At claims 25-26, "A" should be changed to ---The-- because each claim refers to a previous claim.

At claim 29, "a DNA construct" should be changed to ---the DNA construct--- because it refers to a previous claim.

At claim 30," A" should be changed to ---The-- because it refers to a previous claim.

At claim 31, "a " should be changed to ---the --- because it refers to a previous claim.

At claims 33-34, "a fruiting plant" should be changed to ---the fruiting plant--- because each claim refers to a previous claim.

Claim 7 fails to further limit parent claim 6.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7,11-12, and 23-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 6 are indefinite because what is encompassed by "direct " and " indirect" disruption of the functional expression of the peptide is unclear. The specification does not define "direct" or "indirect" disruption. The phrase is open to individual interpretations, and therefore one would know the metes and bounds of the claims.

Claim 7, depending from claim 4, is indefinite because the polynucleotides of (a) and (b) appear to be different. Claim 4 recites that the polynucleotide of (a) encodes SEQ ID NO: 2, while the polynucleotide of (b) encodes SEQ ID NO: 4. Clarification is required to more clearly define the metes and bounds of the claim.

Claims 11-12, depending from claim 4, are indefinite because the *MdPI* and *MdAP*3 peptides are not encoded by the same nucleotide sequence. Appropriate correction is required to more clearly define the metes and bounds of the claims.

At claims Claim 23-24, the 5'-3' implies operable linkage between (a), (b), and (c). However, it is unclear how the promoter sequence of part (a) and the termination sequence of part (c) can affect the non-coding region of part (b). Can the non-coding region be the promoter or terminator of the gene coding for the *MdPI* or *MdAP3* peptide. Dependent claims 25-26 are included in the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a fruiting plant which has been genetically modified such that it does functionally express SEQ ID NO: 2 and/or 4 or functionally equivalent thereof. The claims are also drawn to said plant containing a polynucleotide encoding said peptide, in which the functional expression of the peptide is disrupted directly or indirectly. The claims are further drawn to said plants that produce pome fruit, and seedless fruits produced by said plants. The claims are also drawn to a part of the polynucleotide encoding SEQ ID NO: 2 or 4 or functionally equivalent variants thereof, a DNA construct comprising said polynucleotide in sense or antisense orientation with respect to a promoter.

Applicant, however, teaches the polynucleotides of SEQ ID NO: 1 and 3 from Apple flower encoding polypeptides termed as *MdPI and MdAP3.* Applicant also teaches that *MdPI* is highly expressed in petals and stamens (Figure 3), and has amino acid sequence identity of 64% to Arabidopsis PI protein, a floral homeotic protein. The expression of *MdPI* was only detected in normal flower buds, and not in apetalous flower buds (Figure 3). Applicant also teaches that a transposon insertion mutation in

the *MdPI* gene is responsible for the parthenocarpic phenotype in three parthenocarpic apple varieties (Figure 5). Therefore, Applicant suggests that the disclosed polynucleotide can be used in producing transgenic plants with parthenocarpic fruits.

Applicant has not taught a transgenic plant with parthenocarpic phenotype as a result of expressing SEQ ID NO: 1 or 3, and it is unclear as to whether the transformation of any fruiting plant with said SEQ ID NO: 1 or 3 will result in seedless fruit in the plant, given the fundamental problem in biology of understanding mechanisms of seed development, as known to one of skill in the art. While transformation of a plant with a desired gene is well within the level of one skilled in the art, the transformation of a plant for a specific phenotype is highly unpredictable. For example, the prior art teaches unpredictability in the inhibition of expression of specific coding sequence via antisense RNA in transgenic plants, due to the variation in the degree of antisense inhibition which resulted in different transgenic clones (see, e.g., BIRD et al, Biology and Genetic Review, vol. 9, pages 220-221 (1991)) and due to the mechanism of inhibition of gene expression by means of antisense mRNA which is not universally effective and is poorly understood (Sandler et al (Plant Molecular Biology, vol. 11, pp. 301-310 (1988), see, e.g., page 301, Abstract; page 302, column 1, top two paragraphs). The antisense expression of tomato polygalacturonase gene taught by Smith et al (Nature, Vol. 334, pp. 724-726 (1988), see, e.g., page 725, paragraph bridging columns 1 and 2) does not produce the predicted change in fruit ripening (senescence). Napoli et al (The Plant Cell, vol. 2, pp. 279-289, 1990) also teach

unpredictability inherent in the co-suppression of genes in transgenic plants (see at least, page 279, Abstract).

Given the lack of sufficient guidance in the specification; the limited working examples; the nature of the invention; and unpredictability inherent as discussed above, one skilled in the would not be able to practice the claimed invention without undue experimentation. Therefore, the invention is not enabled.

In the event that Applicant provides evidence that the expression of SEQ ID NO: 1 or 3 (by antisense or sense suppression) induces production of seedless fruit in a transgenic plant, the enablement will still be limited to polynucleotides encoding SEQ ID NO: 2 and 4, for the reasons set forth below.

Applicant has not provided guidance for the obtention and use of a polynucleotide encoding a functionally equivalent variant of SEQ ID NO: 2 or 4. Applicant has not taught all methods of inhibiting target gene expression in plants. No guidance has been provided as to how and where to modify the disclosed polynucleotides so that it encode variants that retain the biological activity of SEQ ID NO: 2 or 4. Applicant has not described which regions in the full-length polypeptides are responsible for the function or lack of function. Applicant has not taught which fragment of SEQ ID NO: 1 or 3 is sufficient to inhibit the expression of the endogenous target gene. Absent specific guidance regarding functionally equivalent variants and fragments of the disclosed polynucleotides, one skilled in the art would have to isolate and characterize a multitude of fragments of SEQ ID NO: 1 and 3, and a multitude of polynucleotides encoding functionally equivalent variants (as defined in the

specification) of SEQ ID NO: 2 and 4 from various sources and evaluate their ability to affect *MdPI* activity in a multitude of transgenic plants. One would also have to evaluate the ability of said multitude of fragments and functionally equivalent variants to induce parthenocarpic phenotype in transgenic plants. Therefore, given the lack of guidance; lack of working examples; the unpredictability; the state of the prior art, the limited working examples; and the claim breadth as discussed above, the claimed invention is not enabled throughout the broad scope.

See Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence) and page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Written Description

Claims 1-8, 13, 16, 19-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a multitude of polynucleotides encoding functionally equivalent variants of SEQ ID NO: 2 and 4, and a multitude of fragments of SEQ ID NO: 1 and 3 that disrupt the functional expression of a target gene to produce transgenic plant with parthenocarpic phenotype. The claims are also drawn to the

transgenic plants and DNA constructs comprising said polynucleotides. In contrast, Applicant only describes SEQ ID NO: 1 and 3, DNA constructs and transgenic plants comprising said polynucleotides. These are genus claims.

University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) where it states "A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. See also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Applicant has not described the composition and structure of all polynucleotides encoding functionally equivalent variants of SEQ ID NO: 2 and 4, and fragments of SEQ ID NO: 1 and 3. There is known correlation between the structure and function of the disclosed polynucleotides, which would allow a skilled artisan to predictably determine the identity of the members of the genus. Therefore, the specification fails to adequately describe the polynucleotides of the invention as broadly claimed. Therefore, SEQ ID NO: 1 and 3 encoding SEQ ID NO: 2 and 4 are not representative species of the claimed genus. Consequently, the specification has not provided an adequate description for DNA constructs and plants comprising said broadly claimed

polynucleotide. Given this lack of description of representative number of polynucleotides encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that Applicant was in possession of the invention as broadly claimed at the time of filing.

Therefore, weighing all factors above, the claimed invention does not meet the current written description requirements. See, Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

Remarks

The claims are deemed free of the prior art of record.

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

10/28/04

Mai

MEDINA A. IBRAHIM
PATENT EXAMINER